

▼ This medicine is subject to additional monitoring



Sancovir® 200mg film coated tablet safety card

Sancovir® film coated tablet contains 200mg of Favipiravir substance that's used for treatment of novel or re-emerging influenza virus infections (limited to cases in which other anti-influenza virus agents aren't effective or insufficiently effective). Its reference drug; "Avigan" approved in Japan for treatment of influenza since 2014.

Mechanism of action:

Favipiravir mechanism involves inhibition of RNA-dependent RNA polymerase enzyme which is used in transcription and replication of the viral genome.

Dosage and administration

The usual adult dose is 1600mg orally twice daily for one day followed by 600mg orally twice daily for 4 days. The total administration period should be 5 days.

Precautions :

Administer the drug only for appropriate patients and inform them and their family about the safety and efficacy of Sancovir® since the safety and efficacy of drug for proposed indication is based on clinical trials with dose level lower than the used dosage.

When you decide to prescribe Sancovir® 200mg tablet, please read Sancovir® leaflet and SmPC carefully. we want to inform you about major precautions to be taken in the following specific groups:

Pregnancy:

- **Sancovir®** is contraindicated in pregnant woman or in woman suspected to be pregnant since teratogenicity and embryonic deaths have been reported in animal studies and therefore the following measures should be taken :
- Negative pregnancy test should be confirmed before starting the treatment for women with childbearing age.
- Effective contraceptive method should be used by woman with childbearing age during and 7 days after the end of treatment.
- Effective contraceptive method (Condom) should be used by men since the drug is distributed in sperm, during and 7 days after treatment and instruct them not to have sexual intercourse with pregnant woman.
- If pregnancy test is suspected during the treatment, Sancovir® drug should be discontinued.

Lactating woman

- Instruct lactating woman to stop lactating during treatment (The metabolites of reference drug was found to be distributed in breast milk).

Children

- Don't administer Sancovir® drug for children (The safety and efficacy of Favipiravir hasn't been established in this age group).

Elderly:

- Sancovir® should be administered carefully for this age group since they have reduced physiological function.

Patients with Hyperuricemia:

- Sancovir® should be administered carefully for patient with gout or patients with history of Hyperuricemia (Sancovir® may increase uric acid level).

Patient with influenza virus infection:

- Abnormal behavior that leads to fall accident may occur in patients who administer Sancovir® treatment, so preventive measures should be implemented at least for 2 days after onset of fever.

(This card focuses on major safety information for medicinal products in order to minimize possible side effects that arise from improper use of medicinal products).

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